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REMARKS

Applicants respectfully traverse the Examiner's restriction for at least the following reasons.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent or distinct as claimed; **and**

(2) There must be serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that (1) the two groups of restricted claims are properly presented in the same application; (2) undue diverse searching would not be required; and (3) all claims should be examined together.

The Examiner has not shown that examination of all the pending claims for human and mouse tyrosinase would require undue searching and/or place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. In fact, applicants submit that to properly search any one group, other group classifications must be considered as well to perform a comprehensive search. Human and mouse gene information is inter-related and when searching anyone group, the other group would need to be searched for completeness.

Specifically in this case, is the restriction requirements not met. **The cited class for both groups is class 514 and the cited subclass is also the same, subclass 44.** To search prior art in the same class and subclass cannot be deemed "undue diverse searching", especially when as can been seen in the attached article, the mouse is genetically similar to the human and it would be more likely than not, that both would appear in a prior art document. Accordingly, the applicants respectfully traverse the requirement for restriction at least on the grounds that examining the identified groups would not be unduly burdensome.

For the above reasons, it is respectfully requested that the Examiner rejoins Groups I and II because there is believed to be no undue or serious burden placed on the

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Examiner in a search of the art. It is believed that the elected claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited.

Respectfully submitted,

Date: January 18, 2007

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The Mouse in Science: Why Mice?

Among the animals used in research, teaching, and testing, mice comprise a majority of all experimental mammals. The remarkable genetic similarity of mice to humans, combined with great convenience, perhaps accounts for mice so often being the experimental model of choice in research. Mice also are used to test new procedures and drugs for safety, as required by an array of federal regulations. Another primary use of mice is for the production of biological reagents, such as monoclonal antibodies and vaccines.

The Handiest Mammal

Besides being genetically similar to humans, mice are small and inexpensive to maintain. Their short life span and rapid reproductive rate make it possible to study disease processes in many individuals throughout their life cycle.

How are They Used?

* Testing: Mice are used to evaluate the safety of new chemicals or products such as household cleaners and pesticides that may be potentially toxic to humans. Mice are also used to assess the safety of drugs and vaccines made for medical use.

Toxicity tests are performed to measure the effects of limited or repeated, long-term exposure of an animal to a particular substance. Other tests measure the extent to which the substance damages cells and causes cancer, mutations in DNA, and birth defects.

The LD50 test, developed in 1927, made it possible to derive a numerical index of toxicity reflecting the lethal dose of a test substance. The test substance was administered to the animal by feeding, injecting, inhalation, or application to the skin. A major drawback to the LD50 test was that it used large numbers of animals. Although it is one of the most well known toxicity tests, it is being replaced by tests using fewer animals that do not require death of the animal as an endpoint.

* Biomedical Research:

Mice are used in biomedical research as models of human beings in order to understand the human body, determine the effects of diseases, and develop treatments for diseases. The nude mouse is used to study cancer. Its immunodeficient status allows human tumors to be grafted onto the mouse without rejection. This

procedure allows for the study of specific human cancers and the testing of new treatments.

Education and Teaching:

Mice and other mammals are used in biological, medical and veterinary education. High school and college students commonly perform dissections on cats, fetal pigs, or other animals to learn about anatomy. Students in medical and veterinary schools use animals to learn and practice surgical and other medical procedures. Far fewer mice and other animals are used in teaching than in testing and research.

Legislation

The United States Animal Welfare Act as revised in 1985 includes most mammals, but excludes laboratory rats and mice. Research institutions voluntarily can seek accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). Accreditation assures that an institution is in conformance with the *Guide for the Care and Use of Laboratory Animals*, which applies to all laboratory animals, including rats and mice. This conformance with the Guide is a requirement for funding by many federal agencies, such as NIH. Hence, most academic institutions seek accreditation and provide the same level of oversight for the care of mice as for other mammals.

For industries or testing facilities that do not seek funding and house only rats and mice, legislation and accreditation requirements do not apply. These institutions would only retain an institutional animal care and use committee as a proactive measure to assure optimal animal welfare, not as a regulatory requirement. One drawback of mice not being regulated is that no accurate figures are available concerning the numbers of mice used in the United States.

How Many?

Without systematic reporting in the United States, accurate estimates of numbers of mice used are not available. However, Great Britain used 1,448,960 mice in 1992, 49% of their total vertebrate animals used. In comparable figures from the Netherlands, 378,834 mice were 43% of all animals used. Rough estimates in the United States range upwards from 6 million mice, presumably accounting for at least half of all mammals used per year.

Quality of Life

Induced genetic defects and research procedures sometimes cause pain and suffering to laboratory mice that may be somewhat alleviated by appropriate analgesia and anesthesia. Enhancing the quality of life for mice may partially offset some of their discomfort. For example, living in social groups would be a more normal situation than solitary housing. Caregivers also can enrich the physical environments of mice by considering the housing. Mice provided with hardwood shavings burrow and build nests. Placing hay or straw on racks above cages allows mice to pull material into the cage and arrange nests. Plastic tubes offer an artificial burrow space, perhaps shielding mice from illumination that may be too bright. Simple enrichments such as these can provide mice some control over their environment.

One complication is that immunodeficient mice require sterile environments. All cage materials used for them, including bedding, food and water, must be autoclaved for sterilization before use. Thus, offering an improved quality of life requires more effort and cost when dealing with those mice that are especially valuable for studies of human diseases.

Alternatives

Alternatives to using mice in testing, research and education involve the concepts of replacement, reduction and refinement. The numbers used can be reduced, and the procedures can be more refined to provide mice a better quality of life or reduce their pain or suffering. Whenever possible, the use of animals can be replaced with improved methods.

*** Testing and Research**

Human studies:Humans who are injured or sick can be studied during recovery and treatment.

In vitro techniques:Tissue and cell cultures can be used to screen certain chemicals before using whole animal toxicity tests.

Mathematical or computer modelling:A simplified version of an organism that sometimes helps in understanding complex systems; variables are entered into a computer and outcomes considered through a model.

Use of less sentient organisms:Invertebrates, such as jellyfish, can be used to detect toxic qualities of chemicals; plants or plant cells can be used to test phototoxins.

Education

Computer simulations:Virtual software on anatomy replaces dissection.

Demonstration and clinical participation:</UL Mentoring is expanded in laboratory and clinical settings.

Ethical Questions
* Should it be possible to patent a mouse strain that carries a gene for a human disease?

* Do mice experiencing adverse circumstances, such as radiation or general discomfort, merit compensatory enhancements in their care?

* Should there be limits to the extent of induced genetic pathology?

Mouse by Design: Some Strain Types
Inbred: Mice that are predisposed to getting a certain disease or genetic defect; they are genetically identical due to inbreeding.

Transgenic: Mice that have been genetically engineered and altered by injection of one or more genes, such as human breast cancer.

Immunodeficient: Mice used in cancer and AIDS research that have minimal immune function, including nude mice and mice with severe combined immune deficiency (SCID).

Knockout: Mice that are engineered to lack a specific gene.

Germfree: Mice that are free from all detectable viruses, bacteria and parasites.

The Mouse in Science is published by the UC Center for Animal Alternatives. The UCCAA mission is to disseminate information concerning animal alternatives so as to improve the well-being and quality of life of animals wherever possible, and to optimize their contribution to education and research.

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